MAR 1 3 2014

510(k) SUMMARY

510(k) Notification K133832 (pg 1/3)

GENERAL INFORMATION

Applicant:
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United States
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Contact Person:
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Product Development Engineer
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United States
Phone: 801-486-6070
FAX: 801-486-6117

Date Prepared: December 16, 2013

DEVICE INFORMATION

The Klassic HD™ Offset Femoral Stem is a modular femoral prosthesis to be used within the Klassic HD™ Hip System to help surgeons restore hip joint biomechanics intraoperatively by helping to achieve proper leg length and offset in total hip arthroplasty.

Trade Name:
Klassic HD™ Offset Femoral Stem

Generic/Common Name:
Femoral Hip Stem

Classification:
21 CFR § 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

Product Code:
LPH, MBL, LWJ

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PREDICATE DEVICES

The Klassic HD Offset Femoral Stem is substantially equivalent in intended use, design, function and performance testing to the following predicate devices:

- Klassic HD Hip System – Total Joint Orthopedics K100445
- Alloclassic Zweymuller SL Offset Femoral Stem – Centerpulse Orthopedics K033664

INTENDED USE

The Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (ID): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

PRODUCT DESCRIPTION

The Klassic HD Offset Femoral Stem is a femoral component to be used within the Klassic HD Hip System as a prosthesis designed to help surgeons restore hip joint biomechanics intraoperatively by helping to achieve proper leg length and offset. The Klassic HD Offset Femoral Stem is offered in both porous and non-porous options. Each configuration of the Klassic HD Offset Femoral Stem is offered in 9 sizes, is sterilized by gamma irradiation and is intended for single-use only.

TECHNOLOGICAL CHARACTERISTICS

The Offset Femoral Stem is a monolithic, titanium alloy, Zweymuller blade type stem featuring a neck shaft angle of 121° and increased lateral offset compared to the 131° neck shaft angle from the Klassic HD Femoral Stem. The Klassic HD Offset Femoral Stem utilizes the identical body geometry as the Klassic HD Femoral Stem, distal to the line of resection; along with the identical Ti6Al4V material and porous coated options.

The neck shaft angle of 121° and increased neck length are similar to the Alloclassic Zweymuller SL Offset Femoral Stem featuring a neck angle of 121° and 6.25mm increased lateral offset versus its predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Non-clinical testing was conducted on the Klassic HD Offset Femoral Stem to support a determination of substantial equivalence to the predicate devices. Non-clinical testing was based off of guidance from

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- Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses, Document 1647 dated September 17, 2007
- ASTM F1814-97a – Standard Guide for Evaluating Modular Hip and Knee Joint Components

The performance testing for the Klassic HD Offset Femoral Stem consisted of neck and stem fatigue testing, axial and torsional disassembly evaluation and range of motion determination. The porous coating properties for the Klassic HD Offset Femoral Stem Porous are identical to that of the Klassic HD Femoral Stem Porous. All bench testing and evaluation demonstrates the Klassic HD Offset Femoral Stem is equivalent in regards to safety and efficacy, is suitable for Total Hip Arthroplasty and is substantially equivalent to predicate devices.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Klassic HD Offset Femoral Stem. The Klassic HD Offset Femoral stem is similar to the predicate devices based on technological characteristics, design, non-clinical performance testing, material and intended use. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic HD Offset Femoral Stem is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2014

Total Joint Orthopedics, Inc.
Mr. Ben Casey
Product Development Engineer
1567 E. Stratford Avenue
Salt Lake City, Utah 84106

Re: K133832
Trade/Device Name: Klassic HD™ Offset Femoral Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, LWJ
Dated: December 16, 2013
Received: December 17, 2013

Dear Mr. Casey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133832 (pg 1/1)

Device Name: Klassic HD™ Offset Femoral Stem

Indications For Use:

The Klassic HD™ Hip System is intended for prosthetic replacement without bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis, osteoarthritis, ankylosis, protrusio acetabuli and painful hip dysplasia.
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis.
- Those patients with failed previous surgery where pain, deformity or dysfunction persists.
- Revision of a previously failed hip arthroplasty.
- Patients who require a total hip replacement.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D Frank -S

Division of Orthopedic Devices